

EC Declaration of Conformity



Manufacturer:

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.
No.25, Lane 300, Jinshan Road, Jiangbei District,
Ningbo 315032, China
Tel: 0086 574 83022668
Fax: 0086 574 87637357

whose single Authorized Representative:

DTF TECHNOLOGY srl
via Gressoney 9, 20137 Milano, Italy
tel: +39.02.84893641
fax: +39.02.84718594

We, the manufacturer, herewith declare that the products

Sealing Machine—Selin

meet the provisions of Directive 93/42/EEC and 2007/47/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex V Quality Assurance Medical Devices of Directive 93/42/EEC.

Applied harmonized standards or national standards:

EN60601-1:2006+A1:2013+AC:2012+A12:2014
EN60601-1-2:2015

following the procedure relating to the EC Declaration of Conformity set out in Annex V Production Quality Assurance Medical Devices of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Ningbo Jiangbei Woson Medical Instrument Co., Ltd.

2021/04/28 – Ningbo, China

Place, date



Name: Xie Diyan

Position: Vice General Manager

Signature:

A handwritten signature in black ink, appearing to read 'Xie Diyan'.

Legally binding signature, Function